

SECTION II
REMARKS

Regarding the Amendments

Claim 3 has been amended as set forth in the above Complete Listing of the Claims. As amended, the claims are supported by the specification and the original claims. No new matter has been added, as defined by 35 U.S.C. § 132.

By the present amendment, claims 2, 5 and 11-21 have been cancelled, without prejudice.

Thus, upon entry of the amendments, claims 1, 3, 4, and 6-10 will be pending and under examination.

Rejection of Claims 1-11 Under 35 U.S.C. §112, first paragraph, Enablement

In the Office Action mailed August 20, 2008 the examiner has rejected claims 1-11 under 35 U.S.C. §112, first paragraph as failing to comply with the enablement requirement. Applicants respectfully disagree.

Specifically the examiner has alleged that the claims lack enablement because “for a [sic] invention to be considered enabled by the specification, the specification must provide an enabled means of making an invention and an enabled use for the invention.” (emphasis in original) Applicants respectfully submit that such enablement is present in the specification.

A determination of enablement under 35 U.S.C. §112, first paragraph is based on an evaluation of whether the disclosure, when filed, contained sufficient information regarding the subject matter of the claims as to enable one skilled in the pertinent art to make and use the claimed invention without “undue experimentation.” Applicants assert that the disclosure of the present application is so enabling.

The examiner’s attention is respectfully drawn to the accompanying Declaration under 37 C.F.R §1.132 of Dr. Joseph Bryant, a named inventor of the application. While Example 11 provided in the specification is a prophetic example, Dr. Bryant’s declaration states that he performed such experiments, as described in the specification, in his lab and achieved the predicted results. Specifically, he generated a hCD4 transgenic rat according to the methods of Example 11 and tested those rats to establish the presence of the hCD4 gene and expression of hCD4. Additionally the rats were infected with HIV. The resulting CD4 rats were used to generate a

double transgenic rat, CD4xHIV-1 and are useful in Dr. Bryant's present work in the identification of drugs for treating or preventing other CD4-related diseases and immune disorders.

Also in the specification, on page 20, multiple uses of such CD4 transgenic rats are provided.

“Such animals are described in Example 11, and are useful, in particular, for producing human CD4/HIV transgenic animals...human CD4 transgenic animals can also be used for the assessment of potential therapeutic and preventive HIV drugs and vaccines, as well as to study the pathobiology of HIV-1 infection. These animals are further useful for identifying drugs for treating or preventing other diseases, e.g., immune disorders, involving CD4. Since CD4 is involved in T cell responses, which are implicated in numerous immunological diseases, e.g., autoimmune diseases, the utility of such animals is very broad.”

Therefore one of skill in the art, as verified by the Declaration of Dr. Bryant, would be able to make a transgenic CD4 rat of the invention according to the disclosure and such a rat would have broad utility, such as in generation of a CD4-containing double transgenic rat or in identification of drugs for treating or preventing CD4-related diseases/immune disorders.

Additionally the examiner maintained the rejection of claims 2-11 as lacking enablement. Claims 2 and 11 have been cancelled by the present Response and claims 3, 4, and 6-10 depend directly or indirectly from claim 1. It is therefore submitted that this rejection is moot.

THE REMAINDER OF THIS PAGE IS INTENTIONALLY LEFT BLANK

CONCLUSION

All of Applicants' pending claims 1, 3, 4, and 6-10 are patentably distinguished over the art, and in form and condition for allowance. The Examiner is requested to favorably consider the foregoing and to responsively issue a Notice of Allowance.

The time for responding to the August 20, 2008 Office Action without extension was set at three months, or November 20, 2008. This Response is therefore timely and no fees are believed to be due for the filing of this paper. However, should any fees be required or an overpayment of fees made, please debit or credit our Deposit Account No. 08-3284, as necessary.

If any issues require further resolution, the Examiner is requested to contact the undersigned attorneys at (919) 419-9350 to discuss same.

Respectfully submitted,

Date: November 20, 2008

/steven j. hultquist/
Steven J. Hultquist
Reg. No. 28,021
Attorney for Applicants

Date: November 20, 2008

/kelly k. reynolds/
Kelly K. Reynolds
Reg. No. 51,154
Attorney for Applicants

<p>The USPTO is hereby authorized to charge any deficiency or credit any overpayment of fees properly payable for this document to Deposit Account No. 08-3284</p>
